

Status of the Application

Claims 1-6 and 8 are pending in the present application. Applicant thanks the Examiner for his removal of the §112 rejections and his acknowledgement at page 3 of the Office Action that the applicants have established criticality of the claimed isomers.

The following rejection is currently at issue: Claims 1-6 and 8 are rejected under 35 U.S.C. §103(a), as allegedly obvious over Cook et al. (U.S. Pat. No. 5,554,646) in view of applicants' disclosure at page 11, line 13-25, Cain et al. (WO 97/18320), Chin et al. and Baltes et al. (U.S. Pat. No. 3,162,658).

Applicants believe that the present amendments and the following remarks traverse the Examiner's rejection of the claims.

REMARKS

A. The references do not teach each element of the claims

The Examiner has maintained the obviousness rejection over Cook et al. (U.S. Pat. No. 5,554,646) in view of applicants' disclosure at page 11, line 13-25, Cain et al. (WO 97/18320), Chin et al. and Baltes et al. (U.S. Pat. No. 3,162,658) for the reasons set forth in the prior office action. In response to the Sæbo Declaration, the Examiner states the following:

The declaration fails to establish the fact that the conjugated linoleic acid disclosed by Cook and Cain as recited in the prior office action containing 2% of the isomers identified in the claim herein. Particularly, applicant generated data, proffered to obviate prior art teachings, lacks the probative force accorded data generated by independent, disinterested parties. It is well settled patent law "that it is not a difficult matter to carry out a process in such a fashion that it will not be successful and, therefore, the failures of experimenters who have no interest in succeeding should not be accorded great weight" In re Michalek, 74 USPQ 108, at 109 citing Bullard Company et al v Coe, 147 F.2d 568, 64 USPQ 359.

For the following reasons, Applicants respectfully submit that the Examiner's reliance on this standard is unfounded and that the cited references do not teach each element of the claims.

1. In re Michalek is in conflict with current PTO practice

The decision relied on by the examiner is more than 50 years old. While this case has not been directly overruled, it is in conflict with current case law and PTO practice. In particular, the Examiner's failure to accord the proper weight to the Sæbo Declaration does not conform with proper patent practice according the Manual of Patent Examining Procedure (MPEP). The Examiner must respond to all of the arguments and evidence presented by Applicants. The MPEP states that:

Office personnel should consider all rebuttal arguments and evidence presented by applicants. . . . *In re Beattie*, 974 F.2d 1309, 1313, 24 USPQ2d 1040, 1042-43 (Fed. Cir. 1992). . . . Office personnel should avoid giving evidence no weight, except in rare circumstances. *Id.* See also *In re Alton*, 76 F.3d 1168, 1174-75, 37 USPQ2d 1578, 1582-83 (Fed. Cir. 1996).

* * *

A determination under 35 U.S.C. 103 should rest on **all the evidence** and should not be influenced by any earlier conclusion. See, e.g., *Piasecki*, 745 F.2d at 1472-73, 223 USPQ at 788; *In re Eli Lilly & Co.*, 902 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990). Thus, once the applicant has presented rebuttal evidence, Office personnel should **reconsider** any initial obviousness determination in view of the entire record. See, e.g., *Piasecki*, 745 F.2d at 1472, 223 USPQ at 788; *Eli Lilly*, 902 F.2d at 945, 14 USPQ2d at 1743.¹

Additionally, the Courts have held as follows:

When *prima facie* obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over An earlier decision should not . . . be considered as set in concrete, and applicant's rebuttal evidence then be evaluated only its knockdown ability. Analytical fixation on an earlier decision can tend to provide the decision with an undeservedly broadened umbrella effect. *Prima facie* obviousness is a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself. Though the tribunal must begin anew, a final finding of obviousness may of course be reached, but such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached . . . upon a different record.²

Furthermore:

¹ MPEP §§2144.08; emphasis added).

² *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976).

If a *prima facie* case is made in the first instance, and if the applicant comes forward with a reasonable rebuttal, whether buttressed by experiment, prior art references, or argument, the entire merits of the matter are to be reweighed.³

Accordingly, even if the Examiner had established a *prima facie* of obviousness in the preceding Office Action (and Applicants contend that he did not), the Examiner must respond to the information presented in the Declaration. The above directions of the court and the PTO state that the evidence **must be considered**. These directions do not categorize evidence according to whether it is developed by interested or disinterested parties and do not state that evidence developed by the inventor **may be ignored**. Indeed, the Examiner must start over and reconsider the entire obviousness analysis. Instead of following this proper practice, the Examiner simply decided to ignore the Sæbo Declaration and rely on the reasons for rejections set forth in the prior office action. **There was no reweighing of the merits by the Examiner.**

2. The Examiner's reasoning ignores the holding of the Supreme Court in *Graham v. Deere*

As discussed above, the Examiner concludes that he may ignore the Sæbo Declaration because it is not by a disinterested party. However, the Supreme Court has held in *Graham v. Deere*, 383 U.S. 1 (1966) that the secondary consideration of failure by others must be given weight in an obviousness analysis. This is precisely what is documented by the Sæbo Declaration - the failure to obtain the same results as reported in the prior art references because the prior art references did not analyze for the disputed isomers of CLA.

3. The Examiner is unjustly accusing the Applicants of fraud

The implication of the Examiner's comments regarding the Sæbo Declaration is that the Mr. Sæbo has committed fraud. Applicants respectfully remind the Examiner the applicants have a duty of candor and that submissions by the applicants must be considered as if this duty has been met. See, MPEP, Chapter 2000 and in particular §2010. This means that the data generated by Mr. Sæbo should be viewed as equivalent to that produced by an

³ *In re Hedges*, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986).

allegedly "disinterested" party. There is absolutely no basis, given the duty of candor, to treat the evidence differently.

4. The references do not teach each element of the claims

When the Sæbo Declaration is properly considered, the cited references do not teach each element of the claims. In the Declaration, Mr. Sæbo states that the methods of Cook would have necessarily produced a composition comprising greater than 2% 8,10 and 11,13 isomers of conjugated linoleic acid. Thus, Applicants have provided evidence that the prior art products do not necessarily or inherently contain less than 2% 8,10 and 11,13 isomers.

Furthermore, the Examiner's attention is also directed to the review article attached to Mr. Sæbo's Declaration. This article, Pariza, M.W., Y. Park, and M. E. Cook, "The biologically active isomers of conjugated linoleic acid," *Progress in Lipids Research* 40:283-298 (2001), is authored by the inventors of the cited prior art. At page 287, in section 2.2, they state:

For example, CLA that we typically produce for experimental purposes consists of the *cis*-9,*trans*-11 (40.8-41.1%), *trans*-10,*cis*-12 (43.5-44.9%), and *trans*-9,-*trans*-11/*trans*-10-*trans*-12 (4.6-10%) isomers.

This provides evidence that the CLA compositions of Cook and Pariza contained greater than the claimed less than 2% *trans,trans*; 8,10; and 11,13 isomers.

Thus, the Examiner has not established a *prima facie* case of obviousness because the cited references do not teach each element of the claims. Accordingly, the claims should be passed to allowance.

B. The cited references do not provide a reasonable expectation of success

With respect to reasonable expectation of success, the Examiner stated in the previous office action (dated April 10, 2002) that "[t]he issue is: will a person with ordinary skill in the art be able to make such a composition, the issue is not whether Cook's disclosed method therein can make the claimed composition (in large scale)."⁴ The Examiner further states that

⁴ Office Action, page 3.

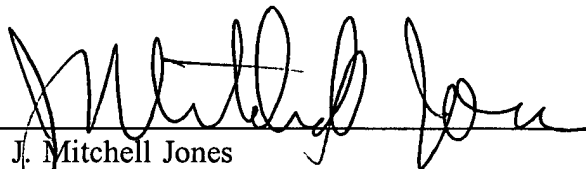
making the claimed compositions is within the skill of the artisan. However, this contention is directly rebutted by Mr. Sæbo's Declaration.

Furthermore, Applicants respectfully submit that Examiner has misstated the standard for expectation of success. Reasonable expectation of success occurs when "the prior art would have suggested to one of ordinary skill in the art that this process **should** be carried out and **would** have a reasonable likelihood of success, viewed in light of the prior art."⁵ Accordingly, contrary to the Examiner's assertion, the prior art (*i.e.*, the references cited by the Examiner) must provide a reasonable expectation of success in producing the claimed compositions. Reasonable expectation of success is determined in the context of what is disclosed in the cited references. Since the cited references do not disclose a method suitable for making the claimed compositions, there can be no reasonable expectation of success. Therefore, Applicants respectfully submit that the Examiner's summary of the issue is not in accordance with patent law standards. Accordingly, the Examiner has not established a *prima facie* case of obviousness and the Claims should be passed to allowance.

Conclusion

All grounds of rejection and objection of the Office Action of April 30, 2001 having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

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⁵ *In re Dow Chemical*, 5 USPQ2d 1529, at 1532 (Fed. Cir. 1988).

APPENDIX I

**CLEAN VERSION OF THE ENTIRE SET OF PENDING CLAIMS AS
AMENDED IN THIS COMMUNICATION**

1. (Amended twice) A food product comprising conjugated linoleic acid alkyl esters in a biologically active concentration, said alkyl esters comprising less than about two percent trans,trans; 8,10 and 11,13 octadecadienoic acid isomers.
2. (Amended once) The food product of claim 1 wherein the concentration of conjugated linoleic acid alkyl esters in said food product is about 0.05 to 3.5 percent by weight.
3. (Amended twice) The food product of claim 1 wherein said conjugated linoleic acid alkyl ester is comprised of at least 50 percent up to about 99 percent by weight of octadecadienoic acid alkyl ester isomers selected from the group consisting of c9,t11-octadecadienoic acid alkyl ester and t10,c12-octadecanoic acid alkyl ester.
4. (Amended twice) A conjugated linoleic acid alkyl ester composition for safe use as a feed, food ingredient, or food supplement obtained by direct isomerization of an unrefined linoleic acid comprising
 - a composition of isomers in one part comprising at least 50 percent by weight of ester isomers selected from the group consisting of c9,t11- octadecadienoic acid alkyl ester and t10,c12-octadecadienoic acid alkyl ester, and combinations thereof, and
 - in a second part comprising less than two percent by aggregate weight of ester isomers selected from the group consisting of 8,10-octadecadienoic acid alkyl esters, 11,13-octadecadienoic acid alkyl esters, and trans,trans-octadecadienoic acid alkyl esters, and
 - in a third part comprising in the range of 0.1 to 0.5 percent phosphatidyl residue remaining after isomerization of said unrefined linoleic acid.
5. (Amended once) The ester composition of claim 4 wherein said c9,t11-octadecadienoic acid alkyl ester contained in said first composition part constitutes greater than 60 percent of the total isomers of octadecadienoic acid alkyl esters.

6. (Amended once) The ester composition of claim 4 wherein said t10,c12-octadecadienoic acid alkyl ester contained in said first composition part constitutes greater than 60 percent of the total isomers of octadecadienoic acid alkyl esters.

8. (Amended once) The food product of claim 1 wherein said conjugated linoleic acid alkyl esters have an alkyl radical selected from the group consisting of methyl-, ethyl-, propyl-, isopropyl-, butyl-, and isobutyl-.